



June 11, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 99N-0438

Dear Sir/Madam:

The Food and Drug Administration asked for scientific data, studies, and other related information concerning issues of contamination of ready-to-eat foods by food preparation employees. Attached to this cover letter is a study that we conducted that addresses this issue.

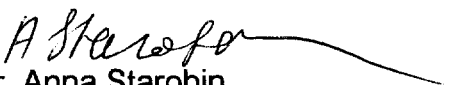
The Food Code of 1999 requires the use of gloves when employees are handling ready-to-eat foods. Research was done in an attempt to demonstrate the effectiveness of gloved hands verses bare hands washed with soap in reducing the transfer of microorganisms.

Transient flora is the main concern when addressing cross contamination issues. Transient bacteria would effect gloved hands or bare hands equally. The attached study results show that transient bacteria from the contaminated, gloved hands had a higher survival rate than those recovered from the washed, bare hands. This higher survival rate would increase the chance of cross-contamination.

It is our belief that there is not enough data collected to support the mandatory use of gloves over hand washing with a good soap in reducing the threat of cross contamination by transient bacterial populations.

We hope that this report will help you in your efforts.

Sincerely,


Dr. Anna Starobin
Microbiology Laboratory Supervisor

99N-0438

C 12

0155 JUN 14 2007



Glove Versus Bare Hand Study

Prepared by microbiology group of
KAY CHEMICAL Co.
1999



LAB REPORT

ACCOUNT: None

DATE: June 10, 1999

ATTENTION:

PREPARED BY: Dr. Anna Starobin

REPORT #:

REQUESTED BY: Dan Brady

COPIES TO:

Objective:

To compare the ability of gloved and bare hands to prevent cross-contamination from the employees hands in the food service environment.

Background:

Food Code, U.S. Public Health Service, FDA, 1999

"Preventing Contamination By Employees

3-301.11 Preventing Contamination from Hands.

(A) FOOD EMPLOYEES shall wash their hands as specified under § 2-301.12.

(B) Except when washing fruits and vegetables as specified under § 3-302.15 or when otherwise APPROVED, FOOD EMPLOYEES may not contact exposed, READY- TO- EAT FOOD with their bare hands and shall use suitable UTENSILS such as deli tissue, spatula, tongs, SINGLE-USE gloves, or dispensing EQUIPMENT.

PERSONAL CLEANLINESS

Hands and Arms

2-301.11 Clean Condition.*

FOOD EMPLOYEES shall keep their hands and exposed portions of their arms clean.

2-301.12 Cleaning Procedure.*

- (A) Except as specified in (B) of this section, FOOD EMPLOYEES shall clean their hands and exposed portions of their arms with a cleaning compound in a lavatory that is equipped as specified under 5-202.12 by vigorously rubbing together the surfaces of their lathered hands and arms for at least 20 seconds and thoroughly rinsing with clean water. EMPLOYEES shall pay particular attention to the areas underneath the fingernails and between the fingers.

2-301.14 When to Wash.*

FOOD EMPLOYEES shall clean their hands and exposed portions of their arms as specified under § 2-301.12 immediately before engaging in FOOD preparation including working with exposed FOOD, clean EQUIPMENT and UTENSILS, and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES and:

- (A) After touching bare human body parts other than clean hands and clean, exposed portions of arms;
- (B) After using the toilet room;
- (C) After caring for or handling SERVICE ANIMALS or aquatic animals as specified in 2-403.11(B);
- (D) Except as specified in 2-401.11(B), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;
- (E) After handling soiled EQUIPMENT or UTENSILS;
- (F) During FOOD preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks;
- (G) When switching between working with raw FOOD and working with READY-TO-EAT FOOD; and
- (H) After engaging in other activities that contaminate the hands."

Therefore, according to the Food Code 1999 hands should be washed frequently, and glove usage is not a handwash replacement. In addition, gloved hands have the same probability as bare hands to become contaminated.

Test Procedure:

- In order to simulate the real restaurant conditions, 19 volunteers were asked to wash their hands with E2 rated antimicrobial handsoap (commonly used in the food industry).
- After 15 minutes a single-use latex glove was applied on the left hand. The right hand was remained ungloved.
- Two by two inch squares (picture1) were drawn on each hands' palm and 0.1 ml of a 24 hour *E.coli* nutrient broth culture was evenly spread on each square.
- The residual *E.coli* was sampled in 15 minutes after application from both gloved and bare hands. Each hand was placed into a plastic bag with 100 ml of a sampling solution, and massaged for 30 seconds. (Massage was performed by two operators working simultaneously on both hands, see picture 2).
- One milliliter of the sampling solution was transferred into 9 ml of Letheen broth in order to interrupt a residual antimicrobial effect of the antimicrobial hand soap used in the beginning of the test.
- The interruption of the killing action of the residual antimicrobial on hands by neutralizer was proven as per ASTM E 1054-91.
- The Letheen broth inoculates were spiroplated on Eosin Methylene Blue (EMB) agar and results recorded after 24 hour incubation at 37°C incubation.
- Statistical analysis of the collected data was performed. The mean differences were tested for significance by the t test.

Notes:

- *Nutrient broth culture was used in order to simulate the soil on the hands.*
- *Palm area of the hand was chosen since this part of the hand is most likely to be in direct contact with food.*

Media:

1. Eosin Methylene Blue agar (BBL)
2. Letheen Broth (BBL)
3. Buffer (pH 7.2) (AOAC)
4. Nutrient Broth (AOAC)
5. Sampling Solution (ASTM 1174-87)

Test culture:

***E.coli* ATCC # 11229**

24-hour Nutrient broth culture.

Results and Observations:

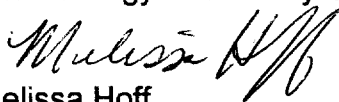
- Results, statistical analysis, proof of the interruption of the killing action of the residual soap, and the test pictures are attached.
- Two to four minutes were needed to dry the bare hand surface while the gloved hand did not completely dry even after 15 minutes of exposure time.
- The single tail t-Test for means on paired samples using the logarithms of the individual bacteria counts showed a p-value of 0.00. This indicates there is a 0.00% chance of seeing this result or one more extreme, given that the population means are identical.

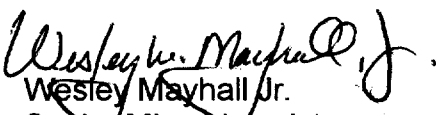
Conclusions and Discussions:


1. Significant E.coli reduction was detected on bare hands versus gloved ones.
2. Factors listed below may be possible contributors to the test results.

<u>Factor Affecting Microbial Growth on Hands</u>	<u>Gloved Hand</u>	<u>Bare Hand</u>
Antimicrobial skin activity	No	Yes
Residual antimicrobial soap activity	No	Yes
Dryness	Yes/No	Yes

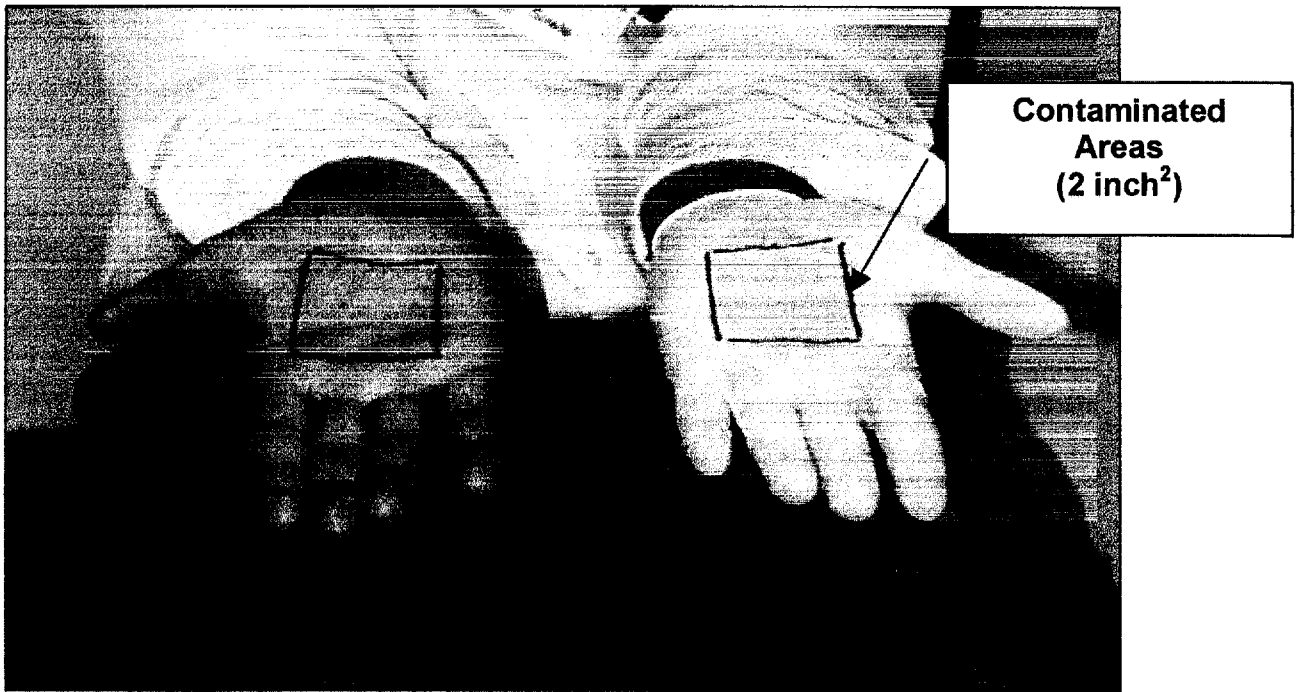

 Dr. Anna Starobin
 Microbiology Laboratory Supervisor


 Melissa Hoff
 Microbiologist


 Wesley Mayhall Jr.
 Senior Microbiologist

Carrie Ermitano
 Technician

 Tim Smith
 Senior Manager Research and Development

Picture 1



Picture 2



Table 1,2

Subject #	Gloved Hand (cfu/ml)	Gloved Hand (log)	Bare Hand (cfu/ml)	Bare Hand (log)	Log Difference Gloved and Bare Hand
1	1.4×10^7	7.2	$<1 \times 10^3$	<3.0	>4.2
2	1.6×10^5	5.2	$<1 \times 10^3$	<3.0	>2.0
3	3×10^5	6.5	$<1 \times 10^3$	<3.0	>3.5
4	3.9×10^5	6.6	8×10^4	4.9	1.7
5	1.1×10^6	6.0		4.3	1.7
6	3.8×10^5	5.6	$<1 \times 10^3$	<3.0	>2.6
7	1.2×10^5	6.1	4×10^4	4.6	1.5
8	LA**	LA**	LA**	LA**	LA**
9	2.8×10^5	5.5	8×10^4	4.9	0.6
10	$<1 \times 10^3$	<3.0	$<1 \times 10^3$	<3.0	0
11	$<1 \times 10^3$	<3.0	$<1 \times 10^3$	<3.0	0
12	$<1 \times 10^3$	<3.0	$<1 \times 10^3$	<3.0	0
13	$<1 \times 10^3$	<3.0	$<1 \times 10^3$	<3.0	0
14	$<1 \times 10^3$	<3.0	$<1 \times 10^3$	<3.0	0
15	7×10^4	4.8	2×10^5	5.3	5.3
16	2×10^4	4.3	$<1 \times 10^3$	<3.0	0
17	6×10^4	4.8	$<1 \times 10^3$	<3.0	0
18	3×10^4	4.5	$<1 \times 10^3$	<3.0	0
19	1.1×10^5	5.0	2×10^4	4.3	0.7

*1000 is a minimum detective level

** LA - laboratory error

t-Test: Paired Two Sample for Means

	<i>Gloved Hand (log)</i>	<i>Bare Hand (log)</i>
Mean	4.83	3.54
Variance	1.91	0.68
Observations	18.00	18.00
Pearson Correlation	0.41	
Hypothesized Mean Difference	0.00	
df	17.00	
t Stat	4.25	
P(T<=t) one-tail	0.00	
t Critical one-tail	1.74	
P(T<=t) two-tail	0.00	
t Critical two-tail	2.11	

Table 3,4

Subject #	Letheen Broth	Letheen broth + Antimicrobial Handsoap
1	4.3×10^6	2.7×10^6
2	4.3×10^6	3.4×10^6
3	4.3×10^6	2.4×10^6
4	4.3×10^6	3.5×10^6
5	4.3×10^6	3.2×10^6
6	4.3×10^6	4.4×10^6
7	4.3×10^6	3.6×10^6
8	LA	LA
9	4.3×10^6	2.3×10^6
10	4.3×10^6	3.6×10^6
11	4.3×10^6	4.3×10^6
12	4.3×10^6	3.2×10^6
13	3.6×10^6	4.4×10^6
14	3.6×10^6	3.7×10^6
15	3.6×10^6	2.6×10^6
16	3.6×10^6	4.6×10^6
17	3.6×10^6	3.9×10^6
18	3.6×10^6	4.7×10^6

t-Test: Paired Two Sample for Means

	Letheen Broth	Letheen broth +soap
Mean	4052941.18	3558823.53
Variance	1.19E+11	5.85E+11
Observations	17.00	17
Pearson Correlation	-0.42	
Hypothesized Mean Difference	0.00	
df	16.00	
t Stat	2.12	
P(T<=t) one-tail	0.03	
t Critical one-tail	1.75	
P(T<=t) two-tail	0.05	
t Critical two-tail	2.12	

Data from the neutralization study was also analyzed by the t-Test for means. The single tail t-Test for means on paired samples of the individual bacteria counts showed a p-value of 0.025. This indicates there is a 2.5% chance of seeing this result or one more extremes, given that the population means are identical.

References:

1. Food Code, FDA 1999
2. Larson, E. A Causal Link Between Handwashing and Risk of Infection? Examination of the Evidence. *Infection Control and Hospital Epidemiology*. 1988;9:28-36.
3. Korniewicz, D. et.al. Integrity of Vinyl and Latex Procedure Gloves. *Nursing Research*. 1989;38:144-146.
4. Snyder, O.P. Handwashing for Retail Food Operations - A Review. *Dairy, Food and Environmental Sanitation*. 18:149-162.
5. Snyder, O.P. Handwashing and Gloving fo Food protection Part II. Effectiveness *Dairy, Food and Environmental Sanitation*. 18:824-829.
6. Larson, E. Handwashing: It's Essential - Even When You Use Gloves. *American Journal of Nursing*. July 1989:934-941.
7. Paulson, D.S. To Glove or to Wash: A Current Controversy. *Food Quality*. June/July 1996:60-63.
8. Troller, J. A. Sanitation in Food Processing. 1983. Personal Hygiene
9. (Chapter 8). New York, N.Y., Academic Press: 166-179.
10. Korniewicz, D. et. al. Leakage of Virus (Bacteriophage X-174) Through Stressed Vinyl and Latex Examination Gloves. (abstract) Fifth International Conference on AIDS held in Montreal, June 1989.
11. Sanitary Gloves May Cause Allergic Reaction. *Food Quality*. October 1996:9.
12. BioScience Laboratories (Bozeman, MT). Use of Gloves by Foodhandlers. April 12, 1996.
13. Kirstein Buck, Ecolab, Inc. Handwashing and Glove Use for Infection Control. *Infection Control Today*, June 1998
14. Abigail A. Salyers and Dixie D. Whitt Bacterial Pathogenesis: A Molecular Approach ASM Press, 1994 pp.5-8
15. Michael J. Pelczar, Jr., E.C.S. Chan, Noel R. Krieg MICROBIOLOGY, Fifth Edition, pp.679-680, McGraw-Hill Book Company

16. ASTM E 1174 –74 Standard Test Method for Evaluation of Health Care Personnel Handwash Formulation.
17. ASTM E 1054 Standard Practices for Evaluating of Antimicrobial Agents Used in Disinfectant, Sanitizer, Antiseptic, or Preserved Products
18. AOAC 16 th Edition, 1995
19. FDA, Bacteriological Analytical Manual, 7th Edition

Place Labels in This Space

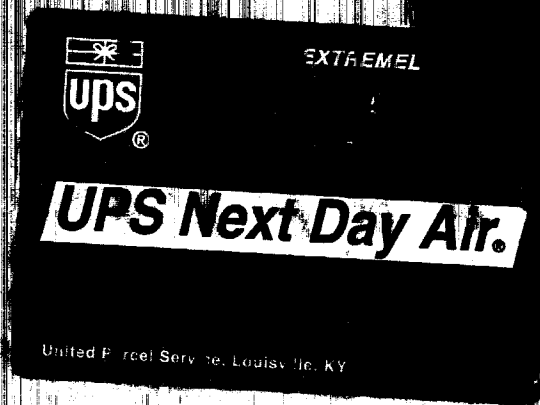
Options: 1 **UPS Tracking Label and your address label**

Place the Tracking Label to the left of the address label.

Stamp your UPS Shipper Number or place parcel register tape above the address label.

2 **UPS Air Shipping Document**

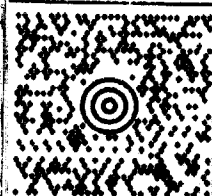
3 **UPS Waybill**



KAY CHEMICAL
(336) 668-7290
8300 CAPITOL DR
GREENSBORO NC 27409-9790

1 LBS

Dockets Management Branch
SHIP FOOD AND DRUG ADMINISTRATION (HFA-30)
TO: 1061
5630 FISHER LANE, Room 1061
ROCKVILLE MD 20852



MD 2070-10



UPS NEXT DAY AIR 1
TRACKING #: 1Z 95X 5X4 01 4258 3072



COSTCENTER: 112

PRO 6.0.1814 E2543



International Shipping Notice - Carriage of Goods by Air (COWA) is subject to the rules relating to liability and other terms and conditions established by the Convention for the Unification of Certain Rules Relating to International Carriage by Air (Montreal Convention), and/or the Convention on the Carriage of Goods by Road (CMR) and/or the Convention on the Carriage of Goods by Sea (Hague-Visby Rules). These conventions, technology or software were exported from the U.S. in accordance with the Export Administration Regulations. Diversion contrary to U.S. law prohibited. For stopping places, call 1-800-752-7862. United Parcel Service, Louisville, KY